UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF NEW YORK

[UNDER SEAL],

Plaintiffs,

v.

[UNDER SEAL],

Defendants.

Case No. 13-cv-5002

FIRST AMENDED COMPLAINT

FILED IN CAMERA AND UNDER SEAL PURSUANT TO 31 U.S.C. §3730(b)(2)

DOCUMENT TO BE KEPT UNDER SEAL

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UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF NEW YORK

UNITED STATES OF AMERICA, and the STATE OF NEW YORK, ex rel. DONNA GERACI and LINDA GIBB, Plaintiffs, vs. ZWANGER & PESIRI RADIOLOGY GROUP, LLP, ZWANGER RADIOLOGY, P.C., and DR. STEVEN MENDELSOHN, Defendants.	Case No. 13-cv-5002 FIRST AMENDED COMPLAINT FOR VIOLATION OF THE FEDERAL and NEW YORK FALSE CLAIMS ACTS **FILED IN CAMERA AND UNDER SEAL PURSUANT TO 31 U.S.C. §3730(b)(2)** **JURY TRIAL DEMANDED**

Plaintiff-Relators Donna Geraci and Linda Gibb, through their attorneys, on behalf of the United States of America (the "Government," or the "Federal Government") and the State of New York ("the State" or the "Plaintiff-State"), for their Complaint against Defendants Zwanger & Pesiri Radiology Group, Zwanger Radiology P.C., and Dr. Steven Mendelsohn (collectively "Defendants" or "Zwanger" and "Dr. Mendelsohn" respectively), allege, based upon personal knowledge, relevant documents, and information and belief, as follows:

I. INTRODUCTION

1. This is an action to recover damages and civil penalties on behalf of the United States of America and the State of New York arising from false and/or fraudulent records, statements, and claims made and caused to be made by Defendants and/or their agents and employees in violation of the federal False Claims Act, 31 U.S.C. §§ 3729 et seq., and the New York False Claims Act, N.Y. State Fin. §§ 187 et seq.

2. Defendants have engaged in a systematic scheme to defraud the United States and New York by fraudulently billing government-funded health care programs for diagnostic imaging tests and/or other medical services that:

(1) were unnecessarily performed on different days solely to evade the Multiple Procedure Payment Reduction rule, in violation of the requirement that services be performed in an economical manner, and in doing so have compromised patient care;

(2) were not ordered by the patient's treating physician;

(3) were never performed; and/or

(4) were ineligible for Medicare reimbursement because they were performed by an uncredentialed physician or at an uncredentialed practice location.

3. Defendants' fraud is not ad hoc or haphazard. Instead, under the express direction of Dr. Mendelsohn, Defendants have created multiple systems to automatically implement the fraudulent schemes. For example, when certain tests are ordered, Defendants' computer systems are set up to automatically schedule additional (unordered) tests that the referring doctor did not order (and that there is no indication the patient needed). If multiple tests are ordered at the same time, Defendants' scheduling personnel schedule the tests for different days to maximize reimbursement. So too, if an uncredentialed physician performs a service, Defendants' computer systems are set up to enable IT personnel to "switch" the provider identification number, practice location, and tax identification numbers so that Medicare and Medicaid are billed as if an eligible provider had performed the test at a credentialed location.

4. Defendants have submitted and caused to be submitted tens, if not hundreds, of thousands of fraudulent claims to federal and state-funded health care programs for unordered, unnecessary, unperformed or otherwise improper diagnostic tests and related services. Each submission is a false or fraudulent claim in violation of the federal and New York False Claims Acts.

5. Defendants' conduct alleged herein violates the federal and New York False Claims Acts. The federal False Claims Act (the "FCA") was originally enacted during the Civil War. Congress substantially amended the Act in 1986 – and, again, in 2009 and 2010 – to enhance the ability of the United States Government to recover losses sustained as a result of fraud against it. The Act was amended after Congress found that fraud in federal programs was pervasive and that the Act, which Congress characterized as the primary tool for combating government fraud, was in need of modernization. Congress intended that the amendments would create incentives for individuals with knowledge of fraud against the Government to disclose the information without fear of reprisals or Government inaction, and to encourage the private bar to commit legal resources to prosecuting fraud on the Government's behalf.

6. The FCA prohibits, inter alia: (a) knowingly presenting (or causing to be presented) to the federal government a false or fraudulent claim for payment or approval; (b) knowingly making or using, or causing to be made or used, a false or fraudulent record or statement material to a false or fraudulent claim; and (c) knowingly making, using, or causing to be made or used, a false record or statement material to an obligation to pay or transmit money or property to the Government, or knowingly concealing or knowingly and improperly avoiding or decreasing an obligation to pay or transmit money or property to the Government. 31 U.S.C. §§3729(a)(1)(A)-(B), and (G). Any person who violates the FCA is liable for a civil penalty of

up to $11,000 for each violation, plus three times the amount of the damages sustained by the United States. 31 U.S.C. §3729(a)(1).

7. The FCA allows any person having information about an FCA violation to bring an action on behalf of the United States, and to share in any recovery. The FCA requires that the Complaint be filed under seal for a minimum of 60 days (without service on the defendant during that time) to allow the government time to conduct its own investigation and to determine whether to join the suit.

8. The New York False Claims Act prohibits similar conduct as that prohibited by the Federal FCA, allows plaintiffs to bring an action on the State's behalf, and provides analogous remedies to those provided in the Federal FCA. As set forth below, Defendants' actions alleged in this Complaint also constitute violations of the New York False Claims Act, N.Y. State Fin. §§ 187 et seq.

9. Based on the foregoing laws, qui tam plaintiffs Donna Geraci and Linda Gibb seek, through this action, to recover damages and civil penalties arising from the false or fraudulent records, statements and/or claims that the Defendants made or caused to be while bilking government-funded healthcare programs for diagnostic imaging and related services.

II. PARTIES

10. Plaintiff-Relator Donna Geraci is a billing specialist residing in Long Island, NY. From September 2010 until March 8, 2012, Ms. Geraci was employed by Defendant Zwanger Radiology or Defendant Zwanger Pesiri Radiology. From January 2011 through September 2011 she served as Zwanger Radiology's Billing Supervisor. Her employment was abruptly terminated after she complained to Dr. Mendelsohn and other executives about numerous fraudulent and otherwise improper practices, including matters described herein.

11. Plaintiff-Relator Linda Gibb is a billing specialist residing in Long Island, NY. She has worked for Defendant Zwanger & Pesiri Radiology Group as a Medical Biller in the Medicare Review Department since November 2010. She is certified as a Physician Practice Manager through the American Association of Professional Coders and is currently pursuing certification through the same association as a Professional Coder, Medical Records Auditor, and Professional Compliance Officer.

12. Relators have witnessed many elements of Defendants' fraud first hand. Relator Geraci has seen false bills submitted to Medicare, Medicaid, and other payers. Relator Gibb has seen false bills submitted to Medicare. They have seen confirmation of payment for these false claims. And they have witnessed Dr. Mendelsohn direct others to implement and otherwise approve of the fraudulent policies and practices detailed herein. For example, as described in more detail below, Relator Geraci was directed, at a meeting convened by Dr. Mendelsohn, to falsify previously-denied Medicare and Medicaid claim forms in order to receive payment. Similarly, Relator Gibb received an email in which, on Dr. Mendelsohn's order, Zwanger scheduling personnel were directed not to schedule specified tests together because it would result in reduced reimbursement.

13. Relators have also repeatedly brought their concerns about Defendants' fraudulent practices to their superiors, and have been repeatedly rebuffed, ignored, and/or retaliated against. Soon after joining Zwanger, Relator Geraci learned that Defendants regularly falsified Medicare and Medicaid claims in order to get them paid. She was deeply troubled by this practice and went to several high-level executives in the practice to seek guidance. Each time she was directed to do whatever was necessary "to get the claims paid." Despite her warnings to Defendants that this constituted fraud, Defendants continued to engage in the scheme.

14. Relator Gibb has also complained repeatedly about issues described herein as well as other improper business practices. For example, in January 2013, Relator Gibb informed Dawn Mortenson, Zwanger's Manager of Insurance Revenue and Recovery, that Zwanger was performing vertebral fracture assessments on patients, and being paid for them, despite the fact that the tests had not been ordered by the patients' treating physicians. Ms. Mortenson ignored this complaint and continued billing for the procedures. Similarly, Relator Gibb advised Lorraine Caracappa, Zwanger's Billing Manager, that Zwanger's practice of making all Medicare beneficiaries sign "Advance Beneficiary Notices" before receiving certain tests was improper. This warning was repeated several times to various billing supervisors but the practice continues today. Relator Gibb is confident that her complaint has been brought to Dr. Mendelsohn's attention and that it is at his directive that the practice continues.

15. Defendant Zwanger & Pesiri Radiology Group LLP ("Zwanger Pesiri") is a New York limited liability partnership headquartered in Lindenhurst, New York. Zwanger Pesiri employs over 50 physicians, and owns and operates, directly or through affiliates and/or subsidiaries, ten diagnostic testing facilities in New York. In the last month, Zwanger Pesiri has announced that it will be expanding to an additional six locations. With these new facilities, Zwanger Pesiri will control approximately 30-40% of the diagnostic imaging market in Long Island.

16. Defendant Zwanger Radiology P.C. ("Zwanger Radiology") is a New York professional corporation headquartered in Lindenhurst, New York. In 2010, Defendant Dr. Steven Mendelsohn decided to open a new radiology practice under the Zwanger name in Stony Brook, New York. This location was held under the name and tax ID of Zwanger Radiology.

Relators do not know how the Zwanger locations are currently held but they are all owned wholly or in part by Dr. Steven Mendelsohn and under his operational control.

17. Defendant Zwanger & Pesiri Radiology Group LLP and Defendant Zwanger Radiology P.C. will be referred to together herein as "Zwanger." The Zwanger facilities take in annual revenue in excess of $300 million.

18. Defendant Dr. Steven Mendelsohn is the Chief Executive Officer, Medical Director, and part-owner of Defendant Zwanger Pesiri and Defendant Zwanger Radiology. As the CEO, Dr. Mendelsohn oversees the day-to-day operations of all of Zwanger's locations and has the final say in all operational, billing, and management decisions, large or small. He currently resides in Rockville Centre, NY.

III. JURISDICTION AND VENUE

19. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. § 1331, 28 U.S.C. § 1367, and 31 U.S.C. § 3732, the last of which specifically confers jurisdiction on this Court for actions brought pursuant to 31 U.S.C. §§ 3729 and 3730. In addition, 31 U.S.C. § 3732(b) vests this Court with jurisdiction over the state law claims asserted in this Complaint.

20. Under 31 U.S.C. § 3730(e), and the analogous provisions of New York's False Claims Act, there has been no statutorily relevant public disclosure of the "allegations or transactions" in this Complaint. Even if there had been any such public disclosure, Relator Geraci and Relator Gibb are the original source of the allegations herein because they have direct, independent and material knowledge of the information that forms the basis of this complaint, and voluntarily disclosed that information to the Government before filing.

21. This Court has personal jurisdiction over Defendants pursuant to 31 U.S.C. § 3732(a) because that section authorizes nationwide service of process and because Defendants have minimum contacts with the United States. Moreover, Defendants can be found in and have transacted business in the Eastern District of New York.

22. Venue is proper in the Eastern District of New York pursuant to 28 U.S.C. §§ 1391(b) and 1395(a) and 31 U.S.C. § 3732(a) because Defendants can be found in and/or transact or have transacted business in this district. At all times relevant to this Complaint, Defendants regularly conducted, and continue to conduct, substantial business within this district and/or maintain employees and offices in this district.

IV. APPLICABLE LAW

A. Federal and State-Funded Health Care Programs

23. Various federal and state-funded health care programs pay for radiology diagnostic testing, such as MRIs, ultrasounds, CT scans, and other related services as described in this Complaint. Examples of such payer programs include the following:

1. The Medicare Program

24. Medicare is a federally-funded health insurance program which provides for certain medical expenses for persons who are over 65, who are disabled, or who suffer from End Stage Renal Disease. The Medicare program is administered through the Department of Health and Human Services, Centers for Medicare and Medicaid Services ("CMS").

25. The Medicare program has four parts: Part A, Part B, Part C and Part D. Medicare Part A ("Part A"), the Basic Plan of Hospital Insurance, covers the cost of inpatient hospital services and post-hospital nursing facility care. Medicare Part B, the Voluntary Supplemental Insurance Plan, covers the cost of services performed by physicians and certain

other health care providers, such as services provided to Medicare patients by physicians, laboratories, and diagnostic testing facilities. See 42 U.S.C. §§ 1395k, 1395l, 1395x(s). Medicare Part C covers certain managed care plans, and Medicare Part D provides subsidized prescription drug coverage for Medicare beneficiaries.

26. To administer the Medicare program, private insurance companies act as agents of the Department of Health and Human Services, making payments on behalf of the program beneficiaries and providing other administrative services. 42 U.S.C. §§ 1395h and 1395u. These companies are called "carriers." 42 C.F.R. §§421.5(c). Through local carriers, Medicare establishes and publishes the criteria for determining what services are eligible for reimbursement or coverage. This information is made available to the providers who seek reimbursement from Medicare.

27. Medicare reimburses health care providers for the costs of providing covered health services to Medicare beneficiaries. See 42 U.S.C. § 1395x(v)(1)(A). In order to bill Medicare Part B, a provider must submit an electronic or hard-copy claim form called the CMS 1500 (formerly known as HCFA 1500) to the appropriate Medicare carrier. The form describes, among other things, the provider, the patient, the referring physician, the service(s) provided by procedure code, the related diagnosis code(s), the dates of service, and the amount charged. The provider certifies on the CMS 1500 claim for that the information provided is truthful and that the services billed on the form were "medically indicated and necessary."

28. In addition, each Medicare provider must sign a provider agreement as a condition of participation, and by so doing must agree to comply with all Medicare requirements including the fraud and abuse provisions. A provider who fails to comply with these statutes and regulations is not entitled to payment for services rendered to Medicare patients.

29. At all times relevant to this action, the local carriers that reviewed and approved the claims at issue in this case based their review upon the enrollment information and claim information provided by the Defendants, and relied on the veracity of that information in determining whether to pay the claims submitted by Defendants.

2. The Medicaid Program

30. Medicaid is a public assistance program providing for payment of medical expenses for low-income and disabled patients. Funding for Medicaid is shared between the Federal Government and those states participating in the program.

31. Federal regulations require each state to designate a single state agency responsible for the Medicaid program. The agency must create and implement a "plan for medical assistance" that is consistent with Title XIX and with the regulations of the Secretary of HHS ("the Secretary"). Although Medicaid is administered on a state-by-state basis, the state programs adhere to federal guidelines. Federal statutes and regulations restrict the items and services for which the federal government will pay through its funding of state Medicaid programs.

32. Each provider that participates in the Medicaid program must sign a provider agreement with his or her state. For example, the New York Department of Health requires any prospective Medicaid provider to certify that he or she will: (1) submit claims for payment only for medically necessary services which were actually furnished; and (2) will comply with the rules, regulations and official directives of the department.

3. Other Federal and State-Funded Health Care Programs

33. The Federal Government administers other health care programs including, but not limited to, TRICARE/CHAMPUS, CHAMPVA, the Federal Employee Health Benefit Program, and federal workers' compensation programs.

34. TRICARE/CHAMPUS, administered by the United States Department of Defense is a health care program for individuals and dependents affiliated with the armed forces. The Federal Employee Health Benefit Program, administered by the United States Office of Personnel Management, provides health insurance for federal employees, retirees, and survivors. 10 U.S.C. §§ 1971-1104; 32 C.F.R. § 199.4(a).

35. CHAMPVA, administered by the United States Department of Veterans Affairs, is a health care program for the families of veterans with 100 percent service-connected disability. 38 U.S.C. §§ 1781-1786; 38 C.F.R. § 17.270(a).

36. The Federal Employee Health Benefit Program, administered by the United States Office of Personnel Management, provides health insurance for federal employees, retirees, and survivors. 10 U.S.C. §§ 1971-1104; 32 C.F.R. § 199.4(a).

37. New York provides health care benefits to certain individuals, based either on the person's financial need, employment status, or other factors. To the extent those programs are covered by the State's False Claims Act, those programs are referred to in this Complaint as "state-funded health care programs."

B. Medicare and Medicaid Only Pay for Medical Services which are Reasonable, Necessary, and Performed Economically

38. Medicare only pays for services that are "medically necessary" – i.e., Medicare requires as a condition of payment that services be "reasonable and necessary for the diagnosis or treatment of illness or injury." 42 U.S.C. § 1395y(a)(1)(A).

39. Further, providers who wish to participate in the Medicare program must ensure that their services are provided "economically and only when, and to the extent, medically necessary." 42 U.S.C. §1320c-5(a)(1).

40. Likewise, the New York State Medicaid program only pays for services which were "actually furnished and which were medically necessary." N.Y. Comp. Codes R. & Regs. tit. 18, § 504.3(e).

41. The requirement of medical necessity is not met when a procedure is performed solely for profit. See U.S. ex rel. Mikes v. Straus, 274 F.3d 687 (2d Cir. 2001) ("the requisite level of medical necessity may not be met where a party contends that a particular procedure was deleterious or performed solely for profit" (citing United States ex rel. Kneepkins v. Gambro Healthcare, Inc., 115 F. Supp. 2d 35, 41-42 (D. Mass. 2000) ("procedures chosen solely for defendants' economic gain are not 'medically necessary' as required by claim submission form"))).

42. Providers may be excluded from participation in the Medicare program and other federally-funded health care programs, if they routinely bill Medicare for medically unnecessary items or services. See 42 CFR § 1003.102.

C. Duty of Providers To Submit Truthful Bills and To Correct Known Errors and Falsehoods in Prior Bills

43. Federal law prohibits providers from making "any false statement or representation of a material fact in any application for any . . . payment under a Federal health care program." See 42 U.S.C. § 1320a-7b(a)(1).

44. Similarly, federal law requires providers who discover material omissions or errors in claims submitted to Medicare, Medicaid, or other federal health care programs to disclose those omissions or errors to the Government. See 42 U.S.C. § 1320-a-7b(a)(3).

45. The requirement that providers be truthful in submitting claims for reimbursement is a precondition for participation in the Medicare program, the Medicaid program and other federally-funded health care programs. See, e.g., 42 CFR §§ 1003.105, 1003.102(a)(1)-(2).

D. Medicare and Medicaid Will Not Pay for Services Performed by Physicians Who are Not Properly Credentialed with each Payer

46. To protect Medicare beneficiaries and the Medicare Trust Funds from unqualified and/or fraudulent providers, all physicians must be "enrolled" with Medicare before they get a Medicare billing number, which allows them to bill the government program. 42 C.F.R. § 424.505. Medicare will not pay claims that do not have a valid Medicare billing number. See 71 Fed. Reg. 20754, 20756 ("Under longstanding policy and operating procedures, any claim submitted without an active billing number is incomplete and cannot be processed for payment.").

47. In order to enroll with Medicare, a provider must submit to CMS the appropriate enrollment application form. 42 C.F.R. § 424.510(d). This application is not just a bureaucratic requirement. The application serves important quality assurance purposes. As part of the enrolling process, each physician must disclose key information about his/her training and

qualifications. A physician who seeks to perform and bill Medicare for advanced diagnostic imaging services must indicate each modality that he/she will furnish (i.e., MRI, CT, NM, and/or PET) and provide the name of the organization that accredited him/her in each modality. Further, the enrolling physician must provide background information about each practice location at which he/she will render services to Medicare beneficiaries. If a physician wishes to change any of his/her identifying information or information about his/her practice locations, a revised form is required.

48. Physicians must certify that all information included in the initial application and any revising application is true, correct, and complete.

49. If a properly credentialed and enrolled physician is absent from his/her practice for a short period, such as for vacation or illness, the practice may retain the services of a substitute physician and bill for the services of that substitute physician under the enrolled (but absent) physician's name and provider number. These arrangements are known as "locum tenens" arrangements. The practice indicates when billing that the enrolled physician did not personally perform the services by including the modifier "Q6" on the claim. This is only proper if the enrolled physician is unavailable to perform the services, the Medicare beneficiary sought services from the absent physician, the practice pays the substitute physician on a per-day or other time-based basis, and the substitute physician does not provide services for longer than 60 days. Medicare Claims Processing Manual, CMS Publication #100-04, Chapter 1, § 30.2.11.

50. Other than with the use of modifier Q6, the claim form must indicate which physician actually performed the services. Medicare will not pay claims for services performed by uncredentialed physicians. Claim forms may not be falsified to indicate that an enrolled

physician performed the billed services when the services were in fact performed by an uncredentialed physician.

51. Similarly, Federal law requires that all providers wishing to bill Medicaid must enter into provider agreements with the relevant state program. 42 U.S.C. § 1396a(a)(27). Further, New York law requires all providers who bill the New York State Medicaid program to "enroll as a provider of services prior to being eligible to receive payments" from Medicaid. N.Y. Comp. Codes R. & Regs. tit. 18, § 504.1(b)(1).

52. To apply for enrollment, an applicant must submit a "complete, original, signed, and sworn application." N.Y. Comp. Codes R. & Regs. tit. 18, § 504.2(b). Payment will not be made for any claims submitted for services, care, or supplies furnished before the enrollment date authorized by the Department of Health.

E. Laws Governing Independent Diagnostic Testing Facilities

53. Medicare will pay for diagnostic tests only if the service is provided by a physician, a group of physicians, an approved supplier of portable x-ray services, a nurse practitioner, an authorized clinical nurse specialist, or an independent diagnostic testing facility ("IDTF"). 42 C.F.R. § 410.33(a)(1).

54. An IDTF is a facility that is separate and independent of a hospital or a physician's office, where patients may go to obtain x-rays, Computed Tomography scans ("CT scans"), magnetic resonance imaging scans ("MRIs"), and other imaging and diagnostic tests that are ordered by the patients' physicians. An IDTF may be a fixed location, a mobile unit, or an individual non-physician practitioner. 42 C.F.R. § 410.33(a)(1).

55. When an entity applies or requests enrollment as an IDTF, the appropriate Medicare carrier obtains certain required information from the entity, such as the tests the entity

intends to bill to Medicare, the names of supervising physicians who are responsible for providing oversight of the equipment and staff and supervising the tests provided by the facility, the supervising physician(s)' Medicare provider number(s) (they must already be Medicare providers), the names and credentials of non-physician technicians who are to perform the tests, and a list of the specific equipment to be used.

56. Upon information and belief, each of Defendants' facilities is an IDTF under the Medicare rules.

1. Diagnostic Tests Performed by IDTFs Must Be Ordered By the Referring Physician

57. Under the Medicare program, all diagnostic tests must be ordered by the physician who is treating the beneficiary. 42 C.F.R. § 410.32(a). Specifically, all procedures performed by an IDTF must be ordered in writing by the physician who is treating the beneficiary. Id. § 410.33(d).

58. The supervising physician for the IDTF may not order tests to be performed by the IDTF, unless the supervising physician is in fact the beneficiary's treating physician. Id. Thus the IDTF may not add any procedures based on internal protocols without a written order from the treating physician. Id.

59. Tests not ordered by the beneficiary's treating physician are considered not reasonable and necessary and, therefore, not reimbursable. Id. § 410.32(a).

2. Diagnostic Tests Must be Performed During a Single Session if Medically Appropriate

60. Medicare recognizes that performing certain procedures in the same clinical session creates efficiencies. Accordingly, in certain circumstances, Medicare pays less for the second, third or subsequent procedure performed during the same session. Effective January 1,

1995, this policy, known as the "Multiple Procedure Payment Reduction" or "MPPR" policy, has applied to certain nuclear medicine diagnostic procedures.

61. The MPPR policy as it applies to diagnostic imaging has been revised several times since originally adopted. Under the current policy, when one or more physicians from a single group practice renders multiple imaging services to a single patient, in a single session, on the same day, full payment is made for the most expensive procedure but payment is reduced for each additional imaging service furnished. Zwanger bills for services globally, i.e. for both the reading doctor's services (the "professional component") and the use of the facilities (the "technical component") in a single bill. The MPPR reduction is slightly different for the professional and technical components but both reductions are wrapped into the global payment. See "Application of the Multiple Procedure Payment Reduction (MPPR) on Imaging Services to Physicians in the Same Group Practice," MLN Matters Number MM7747, August 2, 2012.

62. A "single session" is an encounter where a patient *could* receive one or more radiological studies. 70 Fed. Reg. 70116, 70262. If a patient receives multiple radiological studies in separate encounters on the same day for a medically necessary reason, the provider may append modifier 59 to the additional procedures to indicate that the procedures had to be conducted separately and the MPPR should not be applied. However, use of the modifier when not medically necessary "in order to bypass the payment reduction constitutes fraud." Id. at 70263. Likewise, CMS has directed carriers to establish edits "to ensure that separate sessions are not inappropriately scheduled . . . to bypass the reduction." Id.

63. Services which are performed separately when they could be performed together (i.e., procedures which are unnecessarily "split"), to avoid application of the MPPR rule and to maximize profits for the billing entity, are not performed economically as required by 42 U.S.C.

§1320c-5(a). As such, split services are not "medically necessary" and claims for these services are false and/or fraudulent within the meaning of the Federal and New York State False Claims Acts. This is especially true when the splitting of the procedures requires patients to undergo otherwise unnecessary extra diagnostic testing, ingestion of toxic contrast material, or other unnecessary procedures or care.

64. In US ex rel. Kneepkins, 115 F. Supp. 2d 35, 42 (D. Mass. 2000), the court held that the defendant violated the rule of economic performance by splitting tests, performing half of a panel on one day and the other half the next day to maximize reimbursement. The court reasoned that "the entitlement to Medicare reimbursement depends upon fulfilling an obligation to perform services economically, see 1320c-5(a)(1)" and thus claims for split performance of tests were false because they were "surreptitiously perform[ed] . . . in an intentionally wasteful manner" in violation of this condition of payment. Id. at 43. (Although Kneepkins involved splitting tests, it did not involve application of the MPPR. However, the application of the economic necessity rule is essentially the same.)

65. The Kneepkins court noted that splitting the tests was further improper because by doing so required the patients would require a "needless and intrusive withdrawal of additional blood, with the attendant, (albeit incremental) medical risks." Id. at 42. Performing the tests separately thus "necessarily entailed procedures which were deleterious, inferior, and pursued solely for profit." Id. As such, defendants could not truthfully certify that both tests were medically necessary when performing them separately would necessitate what they knew to be a medically unnecessary blood draw.

V. ALLEGATIONS

A. Defendants Fraudulently and Unnecessarily Performed Procedures on Separate Days Solely to Evade the Multiple Procedure Payment Reduction Rule, in Violation of the Requirement that Services be Performed in an Economical Manner

66. Medicare will only pay for medical services when they are medically necessary and economically performed. Providers may not change the manner of delivery of services solely to increase reimbursement, especially if doing so increases the risk of adverse events to patients even marginally. Claims for services performed in a manner solely to maximize profits, particularly when the chosen manner of performance results in unnecessary services and/or additional patient risk, are false under the Federal and New York False Claims Acts.

67. When physicians refer their patients to Zwanger, they routinely ask Defendants to perform multiple tests on the patient. Solely to maximize reimbursement, and regardless of the health status of the patients, Zwanger's established policy and practice is to split these tests up, requiring patients to return on multiple subsequent days, if performing the procedures on the same day would lead to lower reimbursement for Zwanger. This policy has been in place since at least 2012. Prior policies requiring tests to be read by separate doctors or performed in different sessions may have been used to achieve a similar result, likewise with no benefit to Defendants' patients.

68. Dr. Mendelsohn put this policy in place explicitly to maximize reimbursement. On January 4, 2012, Lorraine Caracappa, Zwanger's Billing Manager, emailed Zwanger's billing department to tell them that because "the proposed Medicare cuts in the professional component of multiple procedures performed on the same day has NOT been postponed . . . Dr. Mendelsohn

has proposed . . . that we do not perform multiple studies on the same day, but schedule patients for one procedure a day....the second the next day."

69. Ms. Caracappa further requested that billing personnel "discreet[ly]" ask the various insurance companies they were responsible for billing what their payment policies were, i.e., how long Zwanger would have to wait between performing tests in order to avoid any reduction in payment. Specifically, Ms. Caracappa requested that, "If this information can be obtained via the internet....please obtain the information in that manner. If not, and you have to contact the insurance company, please ask as a general question." Ms. Caracappa's request that this investigation be done surreptitiously demonstrates Defendants' knowledge that this financially-driven policy was improper.

70. This policy was further articulated in a March 2012 email, in which Chief Executive Assistant to Dr. Mendelsohn, Joy Grimsley, directed Nicole Thristino (Scheduling Personnel Manager) and Jennifer Vita (Operations Personnel Manager), on CEO Robert Day's orders:

> "This is a list of the testing that cannot be done together because of MPPR (Multiple Procedure Payment Reduction)
> If MRI is Scheduled the following cannot be scheduled
> - No 2nd MRI
> - No CT
> - No Sono Abdomen or Pelvis
>
> If CT Scheduled the following cannot be scheduled
> - No MRI
> - No Sono Abdomen or Pelvis
>
> If Ultrasound of Abdomen or Pelvis is scheduled the following cannot be scheduled
> - No MRI

- No CT"

This email was further distributed to the billing department, office managers, ultrasound technicians and others with the directive, "Due to the restrictions in reimbursement from various insurance companies, it has been decided to extend the multiple procedures out to other modalities. Please, review this most recent directive from Administration of the following exams that will no longer be performed on the same day."

71. Zwanger's policy is applied consistently, even if doing so jeopardizes the safety of the patient (e.g., by requiring multiple applications of contrast agent) or violates the referring physician's order for immediate ("stat") performance of the tests.

72. Splitting procedures can be particularly dangerous for patients if the test requires the use of "contrast." Both CT and MRI scans are often performed with the use of a "contrast" agent to provide better images of certain organs and tissue types.

73. For CTs a radiographic iodine-containing dye, known as "iodinated contrast" is administered, most often intravenously. For MRIs the most commonly used contrast agents are gadolinium-based (known as "gado" or "gad"), and are again most often administered intravenously.

74. Both iodinated contrast and gadolinium based contrast agents ("GBCA") can be toxic and repeated administration should be avoided. Iodinated contrast is toxic to the kidneys and scientific research suggests that contrast-induced nephropathy may lead to increased mortality and morbidity, particularly in patients with chronic kidney disease and/or diabetes. Similarly, the FDA has noted an association between administration of GBCA and the serious, sometimes fatal, condition known as nephrogenic systemic fibrosis (NSF). In September 2010, the FDA imposed a requirement that all GBCAs carry warnings about the risk of NSF following

administration. Research has shown that NSF may follow the administration of any gadolinium-based contrast agent, but the risks are particularly high with certain brands of agents and when used in patients with kidney disease.

75. Zwanger's fiscally-driven scheduling policy harms patients because it results in medically unnecessary repeated administrations of contrast. Despite the known toxicity of diagnostic imaging contrast agents, Zwanger often forces patients to come back two, three, or more times, each time receiving an additional dosage of contrast for tests that could, and should, have been performed on the same day, simply to avoid the payment reduction they would be forced to accept if a single dosage of contrast was given and all tests were taken on the same day.

76. For example, one Medicare beneficiary was referred to Zwanger for an MRI of the brain, cervical spine, and thoracic spine, all to be imaged with and without contrast. Zwanger scheduled him for an MRI of the brain on [redacted], an MRI of the cervical spine on [redacted], and an MRI of the thoracic spine on [redacted]. Because the images were ordered with and without contrast, he was administered a gadolinium-based contrast agent all three days. The scheduling of the testing was not only medically unnecessary and inefficient, it placed the patient in greater danger by repeatedly administering a contrast agent known to be toxic. Relator Gibb reviewed Zwanger's Medicare payment records and confirmed on [redacted] that Medicare paid the full fee schedule amount (i.e., without the MPPR reduction that would have been applied if the tests were performed the same day) for these three imaging tests.

77. Likewise, in [redacted], a 66 year old Medicare beneficiary was referred to Zwanger for MRIs of her cervical spine, lumbar spine, thoracic spine, and sacrum, all to be performed with contrast. Zwanger performed an MRI of her spine on [redacted], an MRI of her lumbar spine on [redacted], an MRI of her thoracic spine on [redacted], an MRI of her pelvis on

[redacted], and an MRI of a non-joint lower extremity on [redacted]. Because these tests were ordered with contrast, she was administered an injection of gadobutrol on all 5 days. Relator Gibb confirmed (again, by consulting Zwanger's Medicare records) on [redacted] that Medicare paid the full fee schedule amount for all five imaging tests.

78. By splitting the tests, Zwanger also often forces the patient to undergo (and Medicare to pay for) pre-procedure blood testing, for which, as discussed below, Zwanger fraudulently bills for a blood draw procedure that is never performed.

79. For example, one 70 year old Medicare beneficiary was referred to Zwanger in [redacted] for an MRI of the abdomen and pelvis. On [redacted], Zwanger administered a pin-prick (and billed for a venipuncture), a creatinine test, an injection of gadobutrol, and a pelvic MRI. On [redacted], Zwanger administered a pin-prick (again billing for a venipuncture), a creatinine test, an injection of gadobutrol, and an abdominal MRI. On [redacted], Relator Gibb confirmed that Medicare paid for both MRIs at the full fee schedule amount, two venipunctures, two creatinine tests, and two injections of gadobutrol.

80. A further example of Zwanger's refusal to respect orders for immediate "stat" testing if such would hurt Zwanger's bottom line occurred in [redacted]. On [redacted], an 82 year old Medicare beneficiary was referred to Zwanger for MRIs of his right shoulder and upper arm. The order was marked "stat," meaning that the doctor wanted the procedure to be performed immediately. Nonetheless, Zwanger performed one of the tests on [redacted] and delayed the second until [redacted]. On [redacted], Relator Gibb confirmed that Medicare paid at the full fee schedule amount for both of these tests.

81. Of course, this is to say nothing of the disruption and costs to patients of having to repeatedly schedule transportation, follow testing diets, and spend time necessary for pre-and post-test procedures. An example of the ridiculous inconvenience for Zwanger's patients is the case of a 78 year old Medicare beneficiary referred for an MRI of both of her hands and wrists. Because all of these tests are subject to the MPPR, Zwanger made her return for testing 4 days in a row:

- On [redacted] Zwanger performed an MRI on her left wrist;
- On [redacted] she came back for the MRI on her left hand;
- On [redacted] she was back for an MRI of her right wrist; and
- On [redacted] her right hand was tested.

On [redacted], Relator Gibb confirmed that Medicare paid the full fee schedule amount for all four tests.

82. Because of the inconvenience associated with returning to Zwanger on multiple occasions, patients frequently object to this scheduling policy. To enforce the policy, Zwanger employees lie to patients, including Medicare beneficiaries, and tell them that their insurance will not cover the tests if they are performed together.

83. Relator Gibb has noticed recently that physicians who frequently refer patients to Zwanger have begun writing separate scripts when ordering two or more tests for patients. The scripts are written on the same date, follow the same clinical encounter, and give no indication that the ordering physician desires that the tests be performed on separate dates. She believes these physicians are being asked to do this by Zwanger to make Defendants' fraudulent splitting activity less obvious.

84. Below is a table of some representative examples of fraudulently split tests billed to Medicare. On [redacted], Relator Gibb reviewed Zwanger's records and confirmed that these claims were paid by Medicare as indicated below.

85. To protect patient privacy all patient names have been omitted from example claims described in this complaint. Patients will instead be described in general terms (as above) or as "Patient A," etc. (as below). These patient names will be identified to the government in disclosure materials to be provided along with this complaint.

Patient Name	Prescription	Service Date	Services Billed	Paid Date	ICN #
Patient A	MRI thoracic spine with GAD; MRI lumbar spine with GAD	[redacted]	MRI thoracic spine, with and without contrast (72157) Contrast injection (A9385) Creatinine test (82565) Venipuncture (36415) MRI lumbar spine, with and without contrast (72158) Contrast injection (A9385)	[redacted]	[redacted]
Patient B	MRI brain and C-spine, with and without contrast	[redacted]	MRI brain, with and without contrast (70553) Contrast injection (A9385) MRI cervical spine, with and without contrast (72156) Contrast injection (A9385)	[redacted]	[redacted]
Patient C	MRI brain, MRA head, MRA neck with gad, ultrasound carotid	[redacted]	MRI brain without contrast (70551) Duplex scan of extracranial arteries (93880) MRI head without contrast (70544) MRA neck, with and without contrast (70549) Contrast injection (A9385)	[redacted]	[redacted]

Patient D	MRI brain, MRA head and neck	[redacted]	MRI brain without contrast (70551) MRA neck, with and without contrast (70549) Contrast injection (A9385) Creatinine test (82565) Venipuncture (36415) MRA head without contrast (70544)	[redacted]	[redacted]
Patient E	MRI orbits; MRA brain; MRA neck; all with and without contrast	[redacted]	MRI brain, with and without contrast (70553) Creatinine test (82565) Venipuncture (36415) Contrast injection (A9385) MRA head, with and without contrast (70546) Contrast injection (A9385) MRA neck, with and without contrast (70549) Contrast injection (A9385)	[redacted]	[redacted]

86. Medicare will not pay for diagnostic imaging procedures performed in a manner solely to maximize profits, particularly when the chosen manner results in inferior and/or harmful services.

87. Defendants' policy of splitting procedures to maximize profits is applied to all patients including those insured by Medicare, Medicaid, and other government healthcare programs.

88. All of Defendants' claims to Medicare, Medicaid, and other government healthcare programs, that were fraudulently performed in separate diagnostic sessions (e.g., on separate days) to evade the payment reductions of the MPPR, and all accompanying claims for

unnecessary multiple administrations of contrast agent and extra blood tests, are false under the Federal and New York State False Claims Acts.

B. Defendants Bill for Tests Not Ordered by the Patient's Treating Physician

89. Medicare rules provide that an independent diagnostic testing facility may only bill for a diagnostic radiology test when it is ordered by the physician who is treating the beneficiary, because that referring physician is in the best position to know whether such a test is medically necessary. 42 C.F.R. § 410.33(d). The IDTF radiologist may only order a diagnostic test in the rare situation when he or she is the physician treating the beneficiary. Id. Any test that is not ordered by the beneficiary's treating physician is deemed not medically necessary. Id. § 410.32(a). If a reading radiologist wishes to perform a different or additional test, he/she, except in very limited circumstances, may not perform such a test unless a new order is received from the treating physician. See Medicare Benefit Policy Manual, CMS Publication #100-02, Chapter 15, § 80.6.2-3.

90. In certain limited circumstances, interpreting radiologists have circumscribed leeway to alter or augment orders from a treating physician. When an ordering physician does not specify the desired parameters for a diagnostic test, the radiologist at the IDTF may determine independently, without notifying the treating physician, the appropriate test design given the patient's medical history and diagnosis. See Medicare Benefit Policy Manual, CMS Publication #100-02, Chapter 15, § 80.6.4. For example, if a doctor orders an MRI but does not specify whether contrast is to be used, the radiologist may make a determination based on the patient's symptoms, diagnosis, and medical history, whether images should be taken with, without, or both with and without contrast. Further, if an order has "clear and obvious errors that would be apparent to a reasonable layperson, such as the patient receiving the test (e.g., x-ray of

wrong foot ordered)" the radiologist may modify the order without notifying the treating physician. Id. In both of these limited circumstances, deviations from a treating physician's order must be based on evidence-based protocols governing best practices given each patient's condition and/or documented medical reasoning by the radiologist. Additional or modified tests may not be ordered on a routine basis, or based on a protocol designed for reimbursement maximization purposes.

91. Despite the strict limitations on altering a treating physician's orders, when patients are sent to Zwanger for certain tests (e.g., bone density exams, MRIs with contrast, pelvic ultrasounds, etc.), Zwanger automatically schedules the patient to receive additional tests not ordered by the patient's doctor.

92. These extra tests are scheduled automatically by Zwanger's scheduling system and personnel when the patient contacts Zwanger to arrange the test or tests their doctor actually ordered.

93. Zwanger patients regularly complain that they are being charged for multiple tests when they were only referred for one. Zwanger staff members are trained to tell complaining patients that the tests were medically necessary to obtain sufficient imaging. If patients persist in their complaints, Zwanger has a special code, helpfully titled "Not on Script," that Zwanger staff use to write-off the charges for these extra tests if necessary to avoid further scrutiny.

94. One example of a test routinely added by Zwanger is the vertebral fracture assessment. Soon after she began work at Zwanger, Relator Gibb noticed that patients referred for a dual energy x-ray absorptiometry ("DXA") bone density study (CPT code 77080) were also routinely receiving a vertebral fracture assessment (CPT code 77082), even though the second test was not ordered by the referring physician.

95. DXA is a procedure used to measure bone mineral density. It is frequently prescribed for seniors in order to diagnose and monitor osteoporosis. A vertebral fracture assessment, on the other hand, is not a routine screening exam, as is clearly (in bold font) stated in CMS' coverage determinations. Medicare covers this test only when the treating physician has documented symptoms of a fracture and needs the test to guide treatment.

96. Medicare currently pays $33.85 for a vertebral fracture assessment performed by a physician in Long Island, NY.

97. Relator Gibb noticed in reviewing claims that almost every patient referred to Zwanger for a DXA scan also received a vertebral fracture assessment. She confirmed by reviewing referral forms that the vertebral fracture assessment was rarely, if ever, ordered by the referring physician. Further, there is no other indication in the patients' records of their medical necessity. However, this practice continues, despite the lack of medical necessity and the fact that it causes the patients to be subjected to additional, harmful x-ray exposure.

98. Below is a table of some representative examples of cases where Zwanger performed a bone density scan and a vertebral fracture assessment on Medicare beneficiaries despite the fact that they were referred to Zwanger only for the bone density scan. Relator Gibb reviewed Zwanger's records and confirmed that Medicare paid for each of these tests on the date listed below:

Patient Name	Prescription	Service Date	Services Billed	Paid Date	ICN #
Patient F	Bone density	[redacted]	DXA bone density study (77080) Vertebral fracture assessment (77082)	[redacted]	[redacted]
Patient G	Bone Density	[redacted]	DXA bone density study (77080)	[redacted]	[redacted]

			Vertebral fracture assessment (77082)		
Patient H	Bone density	[redacted]	DXA bone density study (77080) Vertebral fracture assessment (77082)	[redacted]	[redacted]
Patient I	DXA bone density	[redacted]	DXA bone density study (77080) Vertebral fracture assessment (77082)	[redacted]	[redacted]
Patient J	DEXA bone density (77080)	[redacted]	DXA bone density study (77080) Vertebral fracture assessment (77082)	[redacted]	[redacted]
Patient K	Bone density, CPT code 77080	[redacted]	DXA bone density study (77080) Vertebral fracture assessment (77082)	[redacted]	[redacted]

99. Relator Gibb has also discovered in reviewing Zwanger claims that when patients are referred to Zwanger for an MRI with contrast, Zwanger routinely takes and bills for images both with and without contrast. Similarly, if Medicare will pay for CT scans with and without contrast, Zwanger bills for such even when the patient is only referred for images with contrast. It may be medically appropriate in some instances for a radiologist to alter a treating physician's order to conform to best medical practices. However, a treating physician's orders may not be automatically changed without reference to evidence-based standards of care or the considered medical judgment of the interpreting radiologist. A treating physician's orders certainly may not be altered simply to increase reimbursement.

100. Below is a table of some representative examples of cases where Medicare beneficiaries were referred to Zwanger for MRIs with contrast. For each of them Zwanger billed Medicare for tests both "with and without contrast." Relator Gibb confirmed on [redacted]

[redacted] that Medicare paid Zwanger for MRI's with and without contrast for each of the below patients:

Patient Name	Prescription	Service Date	Services Billed	Paid Date	ICN #
Patient L	MRI of abdomen with contrast CPT-74182	[redacted]	MRI abdomen, with and without contrast (74183) Cholangiopancreatography (S8037)	[redacted]	[redacted]
Patient M	MRA: head ~~no contrast~~ with contrast	[redacted]	MRA head, with and without contrast (70546)	[redacted]	[redacted]
Patient N	MRI of abdomen w/ contrast (74182)	[redacted]	MRI abdomen, with and without contrast (74183)	[redacted]	[redacted]
Patient O	74182 (MRI abdomen with contrast)	[redacted]	MRI abdomen without contrast followed by with (74183)	[redacted]	[redacted]
Patient P	Cat scan of head with contrast	[redacted]	CT scan head without contrast followed by with (70470)	[redacted]	[redacted]

101. Below is a table of tests that Relator Gibb has confirmed Defendants routinely perform and bill with and without contrast even though the patient's treating physician only ordered images with contrast:

Procedure	CPT Code
MRI brain with and without contrast	70553
MRI abdomen with and without contrast	74183
MRI neck with and without contrast	70543
MRI pelvis with and without contrast	72197
MRI thoracic spine with and without contrast	72157
MRI lumbar spine with and without contrast	

	72158
MRI sacrum with and without contrast	72195
MRA neck with and without contrast	70549
MRA brain with and without contrast	70546
MRA abdomen with and without contrast	74185
CT head with and without contrast	70470

102. Through the same automatic scheduling mechanism described above, Zwanger patients are regularly receiving unordered ultrasound tests, CT scans, and MRAs. For example, nearly all female patients referred to Zwanger for pelvic ultrasounds receive transvaginal ultrasounds in addition. And nearly all female patients referred to Zwanger for transvaginal ultrasounds receive pelvic ultrasounds as well.

103. CPT code 76856 is for complete non-obstetrical ultrasound imaging of the pelvic organs, including the bladder and reproductive organs. CPT code 76830 is for a transvaginal ultrasound of the reproductive organs. These tests may be ordered together but there are situations where only one is medically appropriate.

104. Medicare currently pays $150.29 for a complete transabdominal ultrasound assessment, and $88.85 for a transvaginal ultrasound assessment performed by a physician in Long Island, NY.

105. As described above, when an ordering physician does not specify the desired parameters for a diagnostic test, the radiologist at the IDTF may determine independently, without notifying the treating physician, the appropriate test design given the patient's medical history and diagnosis. See Medicare Benefit Policy Manual, CMS Publication #100-02, Chapter

15, § 80.6.4. An order for a "pelvic" ultrasound may be considered a "generic" order for an imaging of the pelvic region and may be accomplished through a transabdominal ultrasound or a transvaginal ultrasound. For several issues affecting the reproductive organs of women, transabdominal and transvaginal ultrasounds can be complementary procedures and may be ordered and performed together. However, when this is the case, often times only a limited transabdominal ultrasound is necessary (CPT 76857). Moreover, to justify this, there must be documentation in the patient's records of the medical necessity of the extra procedure. Defendant cannot simply always add the extra procedure.

106. Therefore, it may be appropriate in the case of an order for a "pelvic" ultrasound to perform one or more of the tests listed above. However, as with all treatment decisions, the test(s) chosen must be based on the patient's history, symptoms, and any available diagnoses.

107. Defendants abuse their discretion and automatically perform and bill for complete transabdominal and transvaginal tests anytime a pelvic or transvaginal test is ordered for a woman referred to Zwanger.

108. Further, Defendants disregard specific physician orders when the referring physician specifies that a particular form of pelvic ultrasound is desired.

109. For example, in [redacted], a 65 year old Medicare beneficiary was referred to Zwanger for a female pelvic ultrasound. The physician specifically indicated on the order form that *only* a transvaginal ultrasound was ordered (not a transabdominal). Despite this, Zwanger performed and billed for a transvaginal ultrasound (CPT 76830) as well as a complete transabdominal ultrasound (CPT 76856). Medicare paid for both exams on [redacted].

110. In another case in [redacted], a 72 year old Medicare beneficiary was referred to Zwanger for a complete pelvic ultrasound. The referring physician specified the CPT code for

the desired test (76856), thus making clear that this was not a "generic" request. Despite these clear instructions, the patient received, and billed Medicare for, a complete transabdominal ultrasound (76856) as well as a transvaginal ultrasound (76830). Medicare paid for both claims on [redacted].

111. Similarly, again in [redacted], a 66 year old Medicare beneficiary was referred to Zwanger for a transvaginal ultrasound. The referring physician specified the CPT code for the desired test (76830). But despite these instructions, the patient received, and billed Medicare for, a complete transabdominal ultrasound (76856) as well as a transvaginal ultrasound (76830). On [redacted] Relator Gibb confirmed that Medicare paid for both claims.

112. After learning of this issue, Relator Gibb reviewed several claim forms and discovered that Zwanger had programmed its billing system to link transabdominal ultrasounds with transvaginal ultrasounds. Specifically, Zwanger's system describes CPT code 76856 (a complete transabdominal ultrasound) as a "Pelvic with transvaginal sonogram, 76856" and then adds a charge for "transvaginal sonogram, 76830." Therefore, Defendants recognize that these tests are separately payable and link them no matter what test is prescribed.

113. Zwanger has further limited referring physicians' ability to specify the procedures they desire by bundling the transabdominal and transvaginal tests together on its referral form. Some physicians use referral forms provided by Zwanger when referring patients there for testing. At least one referral form distributed by Zwanger bundles the transvaginal test when a pelvic ultrasound is ordered by including a box for referring physicians to check when they want a pelvic ultrasound and indicating in parentheses that this "includes transvaginal" testing.

114. On another of Defendants' pre-printed "Women's Imaging" referral forms distributed to referring physicians, there is an ultrasound check box for "Pelvis & Transvaginal."

The only way a physician could indicate that only one of these tests was desired would be to strike out part of the order form.

115. Below is a table of some representative examples where Medicare beneficiaries referred to Zwanger for pelvic or transvaginal ultrasounds and Zwanger automatically performed and billed for both a complete transabdominal ultrasound and a transvaginal ultrasound. Relator Gibb confirmed on [redacted] that Medicare paid for both tests performed by Zwanger on each patient.

Patient Name	Prescription	Service Date	Services Billed	Paid Date	ICN #
Patient P	Pelvic ultrasound	[redacted]	Complete pelvic ultrasound (76856) Transvaginal ultrasound (76830)	[redacted]	[redacted]
Patient Q	Abdominal sonogram Pelvic sonogram	[redacted]	Complete pelvic ultrasound (76856) Transvaginal ultrasound (76830) Abdominal ultrasound (76700)	[redacted]	[redacted]
Patient R	Pelvic ultrasound	[redacted]	Complete pelvic ultrasound (76856) Transvaginal ultrasound (76830)	[redacted]	[redacted]
Patient S	Pelvic sonogram	[redacted]	Complete pelvic ultrasound (76856) Transvaginal ultrasound (76830)	[redacted]	[redacted]
Patient T	Transvaginal ultrasound	[redacted]	Complete pelvic ultrasound (76856) Transvaginal ultrasound (76830)	[redacted]	[redacted]

116. Likewise, when a patient is referred to Zwanger for a coronary CT angiogram (commonly known as a "CCTA") he/she also receives and is billed for a CT of the chest. A

CCTA is a heart-imaging test in which x-ray images are taken of the heart and great vessels to determine if plaque has built up in the coronary arteries. A CT of the thorax is generally used to examine tissues of the chest.

117. Relator Gibb was told by a member of the Zwanger front desk staff that it was standard protocol to perform and bill for these two tests together, even if the CT chest was not ordered.

118. Despite clear orders for coronary CTAs (CPT 75574), Zwanger patients regularly receive, or at least are billed for, additional CT scans of the thorax (CPT 71250) even though these latter tests are not ordered by the patients' treating physicians.

119. Below is a table of some representative examples where Medicare beneficiaries were referred to Zwanger for coronary CT angiograms and Zwanger automatically performed and billed for an additional CT of the thorax. Relator Gibb confirmed on [redacted] that Medicare paid for both tests performed by Zwanger on each patient.

Patient Name	Prescription	Service Date	Services Billed	Paid Date	ICN #
Patient U	Coronary CTA w calcium score	[redacted]	CTA heart with contrast (75574) CT scan thorax (72150)	[redacted]	[redacted]
Patient V	CTA coronary arteries	[redacted]	CTA heart with contrast (75574) CT scan thorax (72150)	[redacted]	[redacted]
Patient W	CTA coronary arteries	[redacted]	CTA heart with contrast (75574) CT scan thorax (72150)	[redacted]	[redacted]
Patient X	CT coronary artery, slice CTA	[redacted]	CTA heart with contrast (75574) CT scan thorax (72150)	[redacted]	[redacted]

Patient Y	Coronary CTA	[redacted]	CTA heart with contrast (75574) CT scan thorax (72150)	[redacted]	[redacted]
Patient Z	CTA of coronary artery	[redacted]	CTA heart with contrast (75574) CT scan thorax (72150)	[redacted]	[redacted]
Patient AA	CTA coronary artery	[redacted]	CTA heart with contrast (75574) CT scan thorax (72150)	[redacted]	[redacted]

120. When patients are referred to Zwanger for MRAs of the lower extremities, Defendants over-bill Medicare by billing for 4 different services (a total charge of almost $5,400) when only a subset of these tests is necessary.

121. An MRA of the lower extremities (known as a "runoff" study) is an imaging test of the arteries in the legs and is often used to diagnose narrowed or blocked arteries which can lead to poor circulation and pain. The procedure is frequently performed along with an MRA of the pelvis.

122. When patients are referred to Zwanger for a runoff study (frequently with a prescription reading "MRA aorta and lower extremities" or something similar), they receive and are billed for bilateral MRAs of their left and right legs (CPT 73725), as well as an MRA of the abdomen (CPT 74185) and an MRA of the pelvis (CPT 72198). Regularly performing and billing for this number of tests is excessive and medically unnecessary.

123. Below is a table of some representative examples where Medicare beneficiaries were referred to Zwanger for runoff studies and Zwanger automatically performed and billed for

MRAs of the lower extremities, abdomen, and pelvis. Relator Gibb confirmed on [redacted] that Medicare paid for all four tests performed by Zwanger on each patient.

Patient Name	Prescription	Service Date	Services Billed	Paid Date	ICN #
Patient BB	MRA of aorta & runoff vessels	[redacted]	MRA abdomen with contrast (74185) MRA lower extremity with contrast (rt) (73725) MRA lower extremity (lt) (73725) MRA pelvis with contrast (72198)	[redacted]	[redacted]
Patient CC	MRA aorta/lower extremities	[redacted]	MRA abdomen with contrast (74185) MRA lower extremity with contrast (rt) (73725) MRA lower extremity (lt) (73725) MRA pelvis with contrast (72198)	[redacted]	[redacted]
Patient DD	Lower extremity MRA run off	[redacted]	MRA abdomen with contrast (74185) MRA lower extremity with contrast (rt) (73725) MRA lower extremity (lt) (73725) MRA pelvis with contrast (72198)	[redacted]	[redacted]
Patient EE	MRA of aorta & runoff vessels	[redacted]	MRA abdomen with contrast (74185) MRA lower extremity with contrast (rt) (73725) MRA lower extremity (lt) (73725) MRA pelvis with contrast (72198)	[redacted]	[redacted]
Patient FF	MRA aorta/lower	[redacted]	MRA abdomen with contrast (74185)	[redacted]	[redacted]

	extremities, ultrasound abdomen		MRA lower extremity with contrast (rt) (73725) MRA lower extremity (lt) (73725) MRA pelvis with contrast (72198) Ultrasound abdomen (76700)		

124. Based on Relators' experience with Zwanger's systems, policies, and procedures, Relators believe, and on this basis allege, that Defendants' scheduling system automatically adds other unordered tests when patients are referred to Zwanger for certain diagnostic tests. Other instances where this practice occurs will be evident upon a review of Defendants' scheduling systems and protocols.

125. Medicare and other government-funded healthcare programs will not pay for unordered and/or medically unnecessary diagnostic imaging procedures. Accordingly, all of Defendants' claims to Medicare and other government-funded healthcare programs, for tests that were not ordered by the patient's treating physician are false under the Federal and New York State False Claims Acts.

C. Defendants Fraudulently Bill Government Programs for Tests that are Not Performed

126. As described above, contrast agents used in CT scans and MRIs are toxic and particularly dangerous for those with impaired kidney function. Because of this, before contrast agents are given, creatinine tests are frequently performed to test a patient's kidney health.

127. Creatinine is a metabolic waste product that healthy kidneys filter from the blood. The creatinine test measures the level of creatinine in the patient's blood serum. Higher levels indicate that the kidneys are not clearing waste products from the blood as desired.

128. The blood sample to perform the creatinine test can be acquired in one of two ways. The lab may draw a blood sample from the patient's vein (a process known as venipuncture), and then send the sample to a lab for processing. In addition to the payment for the creatinine test itself, Medicare pays an additional $3.00 (80% of which is paid for by Medicare, the remainder covered by the patient) for venipuncture because of the work involved.

129. None of the Zwanger facilities have a lab on-site. Therefore, if they were to perform the creatinine test by taking a full blood draw they would have to send the sample off-site. It would take upwards of 24 hours before Zwanger received the results from the outside lab and only then could they go forward with administering the contrast agent and performing the ordered scan.

130. Alternatively, Abbott labs manufactures a product known as the "i-STAT" system, a hand-held, mobile device that can perform a broad array of tests for diagnostic and treatment indicators, including the creatinine test, utilizing only two to 3 drops of blood. This amount of blood can be obtained through a finger stick. The results from the test are available on the day of the test.

131. Because a finger-stick involves minimal work, however, Medicare makes no additional payment beyond paying for the test itself.

132. Because the delay associated with sending creatinine tests offsite would be unworkable, all of the Zwanger facilities utilize the i-STAT test – and thus venipuncture is not

required or performed for each of its creatinine tests. Zwanger still bills Medicare for venipuncture.

133. Below are some representative examples of claims submitted by Zwanger for venipuncture procedures that were not performed. On [redacted] Relator Gibb confirmed that Medicare paid for each of these claimed venipuncture procedures.

Patient Name	Service Date	Services Billed	Paid Date	ICN #
Patient GG	[redacted]	Creatinine test (82565) Venipuncture (36415)	[redacted]	[redacted]
Patient HH	[redacted]	Creatinine test (82565) Venipuncture (36415)	[redacted]	[redacted]
Patient II	[redacted]	Creatinine test (82565) Venipuncture (36415)	[redacted]	[redacted]
Patient JJ	[redacted]	Creatinine test (82565) Venipuncture (36415)	[redacted]	[redacted]
Patient KK	[redacted]	Creatinine test (82565) Venipuncture (36415)	[redacted]	[redacted]

134. Medicare will not pay for tests that were not performed. All claims submitted by Defendants for venipunctures that were not performed when the creatinine (or other) tests in question were performed are false under the Federal and New York State False Claims Acts.

D. Defendants Falsely State that Services Performed by Uncredentialed Physicians Were Performed by a Qualified Doctor

135. Medicare and/or Medicaid rules provide that they will not pay claims submitted by physicians who are not credentialed and enrolled in the program. These rules also require such credentialing to be specific to the office location where services are to be provided. Medicare and Medicaid simply will not pay claims submitted by uncredentialed physicians. Moreover, except in limited circumstances, Medicare and Medicaid will not pay claims if it

knows that the physician named in the claim is not the physician who actually performed the service.

136. Defendants routinely disregard these requirements and falsify the physician name and/or location listed on the claim forms to get otherwise ineligible claims paid.

137. Relators learned of this fraudulent policy, and how pervasive it was, on an ongoing basis throughout their employment at Zwanger.

138. Beginning in January 2011 Relator Geraci became the Billing Supervisor for Zwanger Radiology. Zwanger Radiology was created in 2010 as a corporate entity to "hold" a new practice location Dr. Mendelsohn was opening in Stony Brook, New York. The Stony Brook location began operating on January 13, 2011.

139. The Stony Brook location had numerous credentialing issues. At first, the radiologists primarily responsible for reading tests from the imaging center were not qualified to submit claims to Medicare and Medicaid from the facility. After these two doctors were properly credentialed to submit claims to Medicare and Medicaid, Zwanger started using physicians based at Zwanger's other locations to read tests performed at Stony Brook even though these other physicians were not credentialed/qualified to bill for services performed at Stony Brook.

140. Relator Geraci knew that tests read by non-credentialed physicians were not eligible for reimbursement from Medicare or Medicaid. Thus, she reached out to multiple Zwanger supervisors in her attempt to fix Zwanger Radiology's billing issues related to these uncredentialed physicians, including Dr. Mendelsohn, Lorraine Caracappa (Zwanger Radiology's Billing Supervisor), and Barbara Hance (Zwanger's Director of Medicaid Billing).

141. In one instance, at a meeting with Dr. Mendelsohn, Mike Hawkins (Strategic Operations Officer), John Fargnoli (CFO), Lorraine Caracappa (Zwanger Pesiri Billing Supervisor), and Patricia Forte (Credentialing Manager), Dr. Mendelsohn directed Relator Geraci to change the practice location and/or the name of the reading doctor on denied claims received by Stony Brook and to resubmit them, including to government payors, to get the claims paid.

142. In another instance, Relator Geraci was directed to meet with Barbara Hance who handled all Medicaid billing. Ms. Hance told Relator Geraci to resubmit the denied Medicaid claims on paper and change the service location to the Medford practice. She told Relator Geraci that in her 15 years with Zwanger, Ms. Forte had never kept up with credentialing, so she regularly changed service locations in order to get Medicaid claims paid.

143. Zwanger's regular practice was to submit bills to Medicaid electronically. But anytime a claim was resubmitted with the reading physician or service location changed in order to avoid denial based on lack of proper credentialing, the claim would be submitted on paper. Therefore, all paper submissions to the New York State Medicaid program over the last 15 years have been false as to the reading physician and/or location of service.

144. Relator Geraci was shocked by Dr. Mendelsohn and Ms. Hance's instructions so she went to Ms. Caracappa in a further attempt to fix the problem. Ms. Caracappa told her that she was to do whatever was necessary "to get the claims paid."

145. During the time that the Stony Brook location was billing for services performed by uncredentialed doctors, Relator Gibb was asked to come in on a Saturday to work overtime for a "special project." She was told that some bills had gone out of the Stony Brook location under Dr. Mendelsohn's name and they needed to be changed to the name of the physician who

had actually performed the service. At the time Relator Gibb didn't understand why these changes were necessary but came to suspect after working on this project that these were claims that had been denied for reasons like lack of medical necessity. If Zwanger Radiology wanted to appeal these decisions it would have to provide supporting documentation. It could not do so if the name of the billing provider did not match the name of the physician on the report. Therefore, Relator Gibb suspects that Zwanger had employees alter the name to the proper physician so that the denials could be appealed.

146. In August 2011, Relator Geraci was moved from Zwanger Radiology to the billing department at Zwanger Pesiri. In this role she learned from several people including Ms. Caracappa, Dawn Mortenson (Manager of Insurance Revenue Recovery), and Ms. Forte that Zwanger Pesiri utilized an automatic system to bill for uncredentialed physicians. This program was known widely internally as "the switch."

147. When a physician joined the practice and was not yet credentialed for one or more locations, Zwanger's computer system would automatically bill all of his services out under Dr. Mendelsohn's name because Defendants knew that Medicare and Medicaid would not pay if the rendering doctor was not properly enrolled. When the physician was credentialed, if ever, "the switch" would be turned off and the bills would begin going out under the name of the physician in fact performing the reading.

148. Before leaving Zwanger, Brian Wuebker, an IT specialist for Zwanger, confirmed to Relator Geraci that "the switch" was an automated process that Dr. Mendelsohn knew was in place. Mr. Wuebker was very upset about the program and said before leaving that he "wouldn't go to jail for Zwanger."

149. Zwanger employs over 50 doctors at a time and experiences regular turnover. As such, "the switch" is almost always in effect for one or more physicians.

150. Relator Gibb has noticed recently that Zwanger has begun using the Q6 modifier when billing for physicians whom Zwanger is in the process of credentialing. The Q6 modifier may be used to indicate that a substitute physician is standing in for the billed physician when the regular physician is unavailable temporarily due to vacation, illness or the like. It may not be used to bill for newly-employed, un-enrolled physicians.

151. Further, Zwanger has recently entered into a relationship with a radiologist group in Florida called Sun Teleradiology. Zwanger sends images taken at its locations in New York to the physicians in the Sun Teleradiology group. The physicians read the images and send their reports to Zwanger which forwards them to the ordering physicians. Zwanger then submits global bills for the diagnostic imaging services and bills under the name of one of Zwanger's Medicare- and Medicaid-enrolled physicians (using a Q6 modifier). This is problematic for a number of reasons. First, it is fraudulent to use the Q6 modifier in this instance because the Florida physicians are not properly considered substitute physicians. Second, these claims should not be billed globally by Zwanger.

152. As of April 1, 2013, global billing for diagnostic images is only available when the professional and technical components are provided by the same billing entity *and* when the exam is rendered and the physician's location while reading the images are in the same payment locality. See CMS Manual System Transmittal 2679, Publication 100-04 Medicare Claims Processing Manual, Chapter 13, Section 150.D Here, the exams are all taken at imaging centers in New York and the interpretations are done by physicians in Florida. Therefore, these bills should be billed through separate claims for the technical component and professional

component. Further, when the professional component is billed separately, the interpreting physician must report his/her location on the claim form. Payment for the professional component will then be based on this payment locality. See id. at Section 150.E. By billing for Sun Radiologist's services in New York, Defendants are receiving higher payments than they would receive if they disclosed (as required) that the professional services were rendered in Florida. For example, the Medicare allowable payment amount for the professional component of an MRI of the brain with and without contrast (CPT 70553, a code frequently billed by Defendants) is $126.14 in Long Island but $115.69 in Tampa, Florida (where Sun Teleradiology is located). Similarly, the Medicare allowable payment amount for the professional component of an MRI of the pelvis (CPT 72917, another code frequently billed by Defendants) is $119.94 in Long Island but $109.91 in Tampa, Florida.

153. Each claim submitted to Medicare or Medicaid where the rendering physician or service location was falsified or where the Q6 modifier was fraudulently added constitutes a false claim under the Federal and New York State False Claims Act.

Count I
False Claims Act
31 U.S.C. §§3729(a)(1)(A)-(B) and (G)

154. Relators reallege and incorporate by reference the allegations contained in paragraphs 1 through 153 above as though fully set forth herein.

155. This is a claim for treble damages and penalties under the False Claims Act, 31 U.S.C. § 3729, et seq., as amended.

156. By virtue of the acts described above, Defendants knowingly presented or caused to be presented, false or fraudulent claims to the United States Government for payment or approval.

157. By virtue of the acts described above, Defendants knowingly made or used, or caused to be made or used, false or fraudulent records or statements material to false or fraudulent claims.

158. By virtue of the acts described above, Defendants knowingly concealed overpayments from the United States Government and failed to remit such overpayments.

159. The Government, unaware of the falsity of the records, statements and claims made or caused to be made by Defendants, paid and continues to pay the claims that would not be paid but for Defendants' illegal conduct.

160. By reason of Defendants' acts, the United States has been damaged, and continues to be damaged, in a substantial amount to be determined at trial.

161. Additionally, the United States is entitled to the maximum penalty of up to $11,000 for each and every violation alleged herein.

Count II
New York False Claims Act
N.Y. State Fin. § 189(1)(a) - (b) and (h)

162. Relator realleges and incorporates by reference the allegations contained in paragraphs 1 through 153 above as though fully set forth herein.

163. This is a claim for treble damages and penalties under the New York False Claims Act.

164. By virtue of the acts described above, Defendants knowingly presented or caused to be presented, false or fraudulent claims to the New York State Government for payment or approval.

165. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the New York State Government to approve and pay such false and fraudulent claims.

166. By virtue of the acts described above, Defendants knowingly and improperly avoided or decreased an obligation to pay or transmit money or property to the New York State Government.

167. The New York State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendants, paid and continues to pay the claims that would not be paid but for Defendants' unlawful conduct.

168. By reason of Defendants' acts, the State of New York has been damaged, and continues to be damaged, in a substantial amount to be determined at trial.

169. Additionally, the New York State Government is entitled the maximum civil penalty of $12,000 for each and every violation alleged herein.

PRAYER

WHEREFORE, Ms. Geraci and Ms. Gibb pray for judgment against the Defendants as follows:

1. That Defendants cease and desist from violating 31 U.S.C. § 3729 et seq. and N.Y. State Fin. §§ 187 et seq.

2. That this Court enter judgment against Defendants in an amount equal to three times the amount of damages the United States has sustained because of Defendants' actions, plus a civil penalty of not less than $5,500 and not more than $11,000 for each violation of 31 U.S.C. § 3729;

3. That this Court enter judgment against Defendants in an amount equal to three times the amount of damages the State of New York has sustained because of Defendants' actions, plus a civil penalty of $12,000 for each violation of N.Y. State Fin. § 189(1);

4. That Plaintiff-Relators Ms. Geraci and Ms. Gibb be awarded the maximum amount allowed pursuant to §3730(d) of the False Claims Act and the comparable provisions of the New York False Claims Act;

5. That Plaintiff-Relators Ms. Geraci and Ms. Gibb be awarded all costs of this action, including attorneys' fees and expenses; and

6. That Plaintiff-Relators Ms. Geraci and Ms. Gibb recover such other relief as the Court deems just and proper.

DEMAND FOR JURY TRIAL

Pursuant to Rule 38 of the Federal Rules of Civil Procedure, Ms. Geraci and Ms. Gibb hereby demand a trial by jury.

Dated: November 16, 2016

By: _____

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